DETAILED ACTION

1. Claims 9-18 and 20-21 are pending.

2. Applicants' IDS filed on 3/20/08 has been acknowledged.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 9-18 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,816,252(IDS reference, of record) in view of Japan Patent No. 61-13243 (IDS, of record) and U.S. Pat. No. 4,623,541 (IDS reference, of record) for the reasons set forth in the office action mailed on 9/20/07.

Applicants' arguments filed on 3/20/08 have been fully considered but they were not persuasive.

Applicants argued that there is no logical reason to combine the teachings of the references to yield the claimed invention. Applicants argued that the '252 patent does not teach the whey product is being given in the water source and whey product contains only 7-12% Ig and is not from blood plasma. Applicants further argued that the '243 publication does not teach removal of albumin and fibrin. Moreover, Applicants argued that the '541 patent does not teach the immunoglobulin concentrate contains at least 15% IgG.

It is noted that claims 1 and 21 are currently amended to recite immunoglobulin concentrate source is from the blood plasma.

As discussed previously, the '252 patent teaches a method comprising the administration of IgG supplements in the water source of an animal, including a post weaning or new born cow for the transfer of passive immunity to said animal (col. 4, lines 64-67, col. 24, lines 55-60, in particular). Col. 4, lines 64-67 of the '252 patent specifically discloses that the filtered product (e.g. IgG from the whey) is dissolved in water to achieve a desired Ig concentration. Furthermore, the '252 patent teaches that 50% of IgG (e.g. IgG concentrate) is purified under ion exchange (Fig 3) and it is well within the purview of optimization to achieve a desired concentration with a liquid source.

Applicants' arguments based on that the '243 publication does not teach removal of albumin is irrelevant as the rejection is based on the combination of the references. One cannot show nonobviousness by attacking references individually. The purpose of reciting Japan Paten 61-13243 is to show the use of IgG as feed supplement to promote weight gain (abstract, in particular). The removal of albumin and fibrin is performed in the '541 patent.

Applicants further argued that the skim milk powder listed in col. 5 of the '541 patent contains 0.52% of albumin (supplied Brennen reference) and argued the '541 patent

teaches albumin containing milk replacer derived from blood plasma. Applicant acknowledges that the '541 patent teaches the administration of a composition comprising IgG from blood plasma. However, Brennen reference discloses the method to yield 0.52% of albumin is performed by centrifugation while the method used in the '541 patent is ammonium sulfate saturation. Brennan reference discloses that the different heat treatment in drying yields different solid compositions (p. 172) and the electrodialysis and ultrafiltration performed by the '541 patent yields different profile of components. Regardless of presence of albumin in the composition or not, the claimed method does not require the claimed supplement to be free of albumin or fibrin. The claimed method recites IgG from the animal plasma source that is separated from fibrin and albumin and the '541 patent teaches defibrination and separation of albumin (claim 1). The '541 patent teaches the use of animal blood plasma-derived immunoglobulins in a liquid feed source provides weight gain and decrease mortality in piglets in concentration encompassing "about 0.1-0.75% or 0.375-3% by weight" and a dose of 0.5g Ig/hd/day or more (Example 1, biological test, in particular). The '541 patent further teaches that the IgG from serum or plasma can be mixed with other nutrients including vitamin, carbohydrates and minerals (col. 5, lines 55-65, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to administer IgG supplement in the water source of animal, including a cow as taught by the '252 patent or to piglet to promote weight gain as taught by Japan Patent No. 61-13243 or to use IgG concentrate as a feed supplement for piglets and to optimize the concentration of IgG for maximum weight gain and growth while decreasing mortality.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the claimed dosages and the claimed additives to achieve a method for weight gain and decrease mortality as taught by the JP '243 patent and the '541 patent and the optimization of various concentration and dosages would be required by animals of different weights and ages with different nutritional and immunological

need are well within the purview of one of skill in the art at the time the invention . Moreover, one of the ordinary skill in the art would have been motivated to substitute a whey IgG derived from animal plasma because the animal plasma provides a convenient source for the high purity immunugloblulins as taught by the '541 patent (col. 3, lines 7-13).

From the teachings of the references, it would have been obvious to one of ordinary skill in the art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Therefore, the combination of references remains obvious.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,816,252(IDS reference, of record) in view of Japan Patent No. 61-13243 (IDS, of record) and U.S. Pat. No. 4,623,541 (IDS reference, of record) as applied to claim 9 above, and further in view of U.S. Pat. No. 5,143,257, (of record) for the reasons set forth in the office action mailed 9/20/07.

Applicants' arguments filed on 3/20/08 have been fully considered but they were not persuasive.

Applicants argued that there is no logical reason to combine the teachings of the references to yield the claimed invention. Applicants argued that the '252 patent does not teach the whey product is being given in the water source and whey product contains only 7-12% Ig and is not from blood plasma. Applicants further argued that the '243 publication does not teach removal of albumin and fibrin. Moreover, Applicants argued

that the '541 patent does not teach the immunoglobulin concentrate contains at least 15% IgG.
In light of discussion above in section 4 of this office action, the combination of references remains obvious.

6. No claims are allowable.

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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